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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,625	11/03/2000	Xiu Xiu Cheng	300.1012	6705

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EXAMINER
WARE, TODD

ART UNIT	PAPER NUMBER
1615	12

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/705,625	Applicant(s) CHENG ET AL.	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4-5, 7-15, and 18-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-5, 7-15, 18-24, and 26-31* is/are rejected.

7)☒ Claim(s) *25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of request for extension of time (granted) and amendment/response all filed 3-4-03 is acknowledged. In view of Applicant's comments and the new grounds for rejection, the instant Office Action is non-final. Claims 2-3, 6, 16-17, and 32-34 have been canceled and claims 1, 4-5, 7-15, and 19-29 have been amended as requested. Claims 1, 4-5, 7-15, and 18-31 are pending.

Claim Objections

1. Claim 18 is objected to because of the following informalities: claim 18 depends from canceled claim 17. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 18 depends from canceled claim 17.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4-5, 7-15, 18-24, 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (WO 00/28989; hereafter '989) in combination with Chiao (Remington, 1995) and further in combination with Drug Facts and Comparisons (1999) **OR** Moeckel et al (5,955,106; hereafter '106) in combination with Chiao (Remington, 1995) and further in combination with Drug Facts and Comparisons (1999).

8. '989 and '106 both teach controlled release metformin compositions but do not teach the exact release profile(s) of the instant claims.

9. Chiao is relied upon for teaching manipulation of controlled release formulations in achieving a desired release profile. Such manipulation can occur, for example, by

varying the controlled release carrier, amount of controlled release ingredients, or thickness of coating(s) of controlled release ingredients.

Drug Facts and Comparisons (DFC) is relied upon for teaching delivery of metformin in the presence or absence of food.

10. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '989 with Chiao and DFC or '106 with Chiao and DFC with the motivation of providing controlled delivery of metformin over a desired period of time to lower blood glucose levels when an individual is in the fed state. Applicant's comments filed 3-4-03, Paper # 11, stating that numerous controlled release technologies are well within the knowledge of pharmaceutical formulators having ordinary skill in the art and such pharmaceutical formulators know that controlled release technologies can be manipulated, e.g. by varying the amount of controlled release carrier (among other things), to provide a formulation which upon *in* vivo testing will provide the T_{max} range of the present invention (pages 8-9 of response), are also relied upon for supporting the above position.

11. Claims 1, 4-5, 7-15, 18-24, 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al (WO 99/47125; hereafter '125) in view of Drug Facts and Comparisons (1999).

12. '125 teaches controlled release metformin compositions but does teach the exact release profile(s) of the instant claims. In addition, '125 discloses a semi-permeable membrane coating surrounding the core. '125 incorporates by reference US Patent No.

3,845,770 (hereafter '770) to further describe the passageway and therefore drug release from the formulations taught therein. Briefly, '770 teaches adjustment of the release profile through manipulation of the interaction between the semi-permeable membrane and passageway(s) of the device (see '770 at C 6, L 39 - C 7, L 21; C 12, L 57 - C 13, L 67).

13. Drug Facts and Comparisons (DFC) is relied upon for teaching delivery of metformin in the presence or absence of food.

14. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to manipulate the release profile of '125 in accordance with the teachings in '770 and lower blood glucose levels accordingly with the motivation of providing controlled delivery of metformin over a desired period of time and to administer the compositions at dinner or at a fed state with the motivation of regulating sugar levels.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 4-5, 7-15, and 18-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,099,859. '859 teaches a semi-permeable membrane metformin formulation and incorporates US Patent No. 3,845,770 (hereafter '770) by reference to further describe the passageway and therefore drug release from the formulations taught therein. '770 teaches adjustment of the release profile through manipulation of the interaction between the semi-permeable membrane and passageway(s) of the device (see '770 at C 6, L 39 - C 7, L 21; C 12, L 57 - C 13, L 67). Accordingly, it would have been obvious to one skilled in the art at the time of the invention to manipulate the release profile of '125 in accordance with the teachings in '770 with the motivation of providing controlled delivery of metformin over a desired period of time.

17. Claims 1, 4-5, 7-15, and 18-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,284,275. '275 teaches a semi-permeable membrane metformin formulation and incorporates US Patent No. 3,845,770 (hereafter '770) by reference to further describe the passageway and therefore drug release from the formulations taught therein. '770 teaches adjustment of the release profile through manipulation of the interaction between the semi-permeable membrane and passageway(s) of the device (see '770 at C 6, L 39 - C 7, L 21; C 12, L 57 - C 13, L 67). Accordingly, it would have been obvious to one skilled in the art at the time of the invention to manipulate the

release profile of '125 in accordance with the teachings in '770 with the motivation of providing controlled delivery of metformin over a desired period of time.

18. Claims 1, 4-5, 7-15, and 18-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,099,862. '862 teaches a semi-permeable membrane metformin formulation and incorporates US Patent No. 3,845,770 (hereafter '770) by reference to further describe the passageway and therefore drug release from the formulations taught therein. '770 teaches adjustment of the release profile through manipulation of the interaction between the semi-permeable membrane and passageway(s) of the device (see '770 at C 6, L 39 - C 7, L 21; C 12, L 57 - C 13, L 67). Accordingly, it would have been obvious to one skilled in the art at the time of the invention to manipulate the release profile of '125 in accordance with the teachings in '770 with the motivation of providing controlled delivery of metformin over a desired period of time.

19. Claims 1, 4-5, 7-15, and 18-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 09/726,193. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are within the scope (species) of the claims of Application No. 09/726,193 (genus).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

20. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

tw
July 10, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600